IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **ALL PLAINTIFFS LISTED IN EXHIBIT A TO PLAINTIFFS' NOTICE OF ADOPTION**	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN RESPONSE TO PLAINTIFFS' MOTION TO EXCLUDE GENERAL OPINION TESTIMONY OF NICOLETTE HORBACH, M.D.

In Wave 3 of this litigation, Plaintiffs adopt the *Daubert* motion they filed as to the general-causation opinions of Nicolette Horbach, M.D., in Wave 1. *See* Pls.' Notice of Adoption (Dkt. 2776). The Court has ruled on that Wave 1 motion. *See In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4582210 (S.D.W. Va. Sept. 1, 2016). Defendants Ethicon, Inc., Johnson & Johnson and, where applicable, Ethicon LLC (Ethicon) respectfully request that this Court again deny Plaintiffs' motion for the reasons expressed in Ethicon's Wave 1 response (Defs.' Opp'n (Dkt. 2183)) incorporated here and as supplemented by the reasons set forth below, and in accordance with this Court's September 1, 2016 Memorandum Opinion and Order.

ARGUMENT AND AUTHORITIES

I. Dr. Horbach's general methodology is reliable.

Plaintiffs assert the same argument critiquing Dr. Horbach's methodology—specifically, her citation style and reliance list—that they advanced in Wave 1. This Court reserved judgment "until the reliability and foundation of specific opinions may be evaluated firsthand at trial." *In re: Ethicon Inc.*, 2016 WL 4582210, at *3. Ethicon reiterates that the Federal Rules of Civil Procedure do not prescribe a specific citation style for expert reports (*see* Defs.' Opp'n (Dkt. 2183) at 2-3), and Plaintiffs have not shown any methodological flaw regarding the opinions expressed in Dr. Horbach's report. In the absence of new argument from Plaintiffs, Ethicon rests on its Wave 1 response, and respectfully requests that the Court deny Plaintiffs' motion or, at the very least, reserve ruling as it did in the Wave 1 cases. *See In re: Ethicon Inc.*, 2016 WL 4582210, at *3.

II. Dr. Horbach is qualified to offer expert opinions on whether there are clinical differences between mechanical-cut and laser-cut mesh, and her methodology is reliable.

Plaintiffs assert the same argument challenging Dr. Horbach's qualifications to opine as to physical and/or clinical differences between machine-cut and laser-cut mesh that they advanced in Wave 1. This Court rejected Plaintiffs' argument, finding Plaintiffs "gross[ly] mischaracteriz[ed]" Dr. Horbach's testimony and that she is "qualified to offer expert testimony of this sort." *Id.* It nonetheless reserved ruling on Plaintiffs' reliability argument until Dr. Horbach's testimony on this subject could be "evaluated firsthand at trial." *Id*. Ethicon respectfully requests that the Court to enter the same ruling for the Wave 3 cases.

III. Dr. Horbach is qualified to testify about the material characteristics of polypropylene mesh.

Plaintiffs assert the same argument challenging Dr. Horbach's qualifications to testify about the material characteristics of polypropylene mesh that they advanced in Wave 1. This Court overruled Plaintiffs' objection, concluding that her "extensive clinical experience, combined with [her] analysis of the relevant literature, qualifies her to opine on mesh's reaction to and effect on the human body." *Id.* at *4. Ethicon respectfully requests that the Court rule in the same manner in the Wave 3 cases and again deny Plaintiffs' motion with respect to Dr. Horbach's qualifications to offer these opinions.

IV. Dr. Horbach's opinion that mesh degradation is not clinically significant is reliable because it is based upon her 30 years' clinical experience as a urogynecologist and review of medical literature.

This Court previously excluded Dr. Horbach's opinions on mesh degradation on reliability grounds, citing concerns with her record-keeping and the microscope she used to examine mesh specimens. *Id.* at *4. Respectfully, Ethicon believes the Court misunderstands the nature of Dr. Horbach's mesh degradation opinion and renews its Wave 1 argument that her opinions on this topic are proper.

Ethicon reiterates that Dr. Horbach has no intention of offering pathology opinions about particular mesh specimens. Although Plaintiffs referred to Dr. Horbach's opinions as "Opinions on Mesh Pathology" (*see* Pls.' Mem. (Dkt. 2045) at 9), she is not offering pathology opinions. Instead, she intends to testify that she has not encountered patients with mesh degradation in 30 years of practice, nor has she seen medical literature showing that mesh degradation occurs in the body (as opposed to as a result of the explant process), so that it is a clinically significant risk factor. As she explained during deposition:

> A. In my experience and my review of the literature I do not think that degradation is a significant or clinical[ly] relevant issue within a patient.
>
> Q. Let me just clarify. It sounds like you're not saying there is not some degree of degradation; you're just saying it's not clinically significant. Is that fair?
>
> A. No, I'm not saying it's not—definitely not clinically significant, and trying to determine if something is a nonclinically significant degradation is difficult to do. I think that the—
>
> Q. Okay.
>
> A. —studies—I'm not done. I think that the studies that have looked at degradation, many of them have not shown degradation to occur in explanted specimens, and the difficulty is, as soon as you explant a specimen, you are creating an artifact in any evaluation of that specimen that can be related to just the process of surgically implanting and/or removing.

Ex. E to Pls.' Mot. (Dkt. 2044-5), Horbach 3/25/16 Dep. Tr. 52:19–53:19. Plaintiffs have pointed to no evidence to impugn what Dr. Horbach has learned from clinical experience and her review of the relevant literature—that there is no evidence of mesh degradation being a clinically significant risk.

Clinical experience and review of medical literature suffices under *Daubert*'s requirement of a reliable methodology. Indeed, as noted above, this Court's September 1 Memorandum Opinion and Order deemed Dr. Horbach's experience, as a "board-certified urogynecologist who has performed thousands of pelvic floor surgeries over the course of her thirty years in clinical practice . . . combined with [her] analysis of the relevant literature" to be both sufficient qualifications and a reliable methodology to support her opinions regarding the material characteristics of polypropylene mesh. *In re: Ethicon Inc.*, 2016 WL 4582210, at *4. So

too here; Dr. Horbach's experience and review of relevant medical literature enables her to opine that mesh degradation is not a clinically significant risk factor.

Accordingly, Ethicon respectfully renews its Wave 1 opposition on this issue with the aforementioned clarification.

V. Dr. Horbach will not testify regarding what should or should not be included in an IFU, but is qualified to testify about the risks of implanting mesh and whether those risks appeared in the IFU, as well as the commonly known risks of mesh.

This Court excluded Dr. Horbach's testimony regarding "what an IFU should or should not include," *id.*, but did not exclude testimony "about how doctors interpret IFUs and what results from misinterpreting an IFU," *id.* at *4 n.2. Further, by citing its decision in *Wise v. Bard*, the Court pointed to the difference between expertise in FDA labeling requirements and a urogynecologist's permissible opinions about product risks and whether the label conveyed those risks. *Wise v. C.R. Bard, Inc.*, No. 2:12–cv–01378, 2015 WL 521202, at *5 (S.D.W. Va. Feb. 7, 2015) ("Dr. Ostergard will testify about the risks he perceives that the Avaulta poses to patients, and he will opine that the Avaulta IFU did not convey these risks. A urogynecologist like Dr. Ostergard is qualified to make this comparison."). Indeed, the Court acknowledged that an experienced urogynecologist like Dr. Horbach *may* "testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU." *In re: Ethicon Inc.*, 2016 WL 4582210, at *4.

In accordance with this Court's limitations, Dr. Horbach will not testify about regulatory requirements for the IFUs at issue here or what the IFU should or should not include. But, as this Court has held, Dr. Horbach is entitled to testify about the specific risks of implanting mesh and whether those risks appeared in the IFU. *Id.*

Further, Dr. Horbach's testimony about whether certain risks were commonly known among pelvic floor surgeons is not inconsistent with this Court's rulings. Indeed, this Court expressed no opinion about expert testimony regarding "whether certain risks were common knowledge," and therefore has not precluded this expert testimony. *See, e.g.*, *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4582231, at *3 n.2 (S.D.W. Va. Sept. 1, 2016) ("The plaintiff's Motion focuses on whether Dr. Woods is qualified to offer expert testimony about what should be included in or what may be excluded from an IFU. So I offer no opinion on whether Dr. Woods may testify about whether certain risks were common knowledge."); *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4557036, at *3 n.2 (S.D.W. Va. Aug. 31, 2016) (same as to Dr. Drolet); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4536875, at *4 n.2 (S.D.W. Va. Aug. 30, 2016) (same as to Dr. Serels); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4542054, at *3 n.2 (S.D.W. Va. Aug. 30, 2016) (same as to Dr. Elser); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4536872, at *3 n.2 (S.D.W. Va. Aug. 30, 2016) (same as to Dr. Sepulveda-Toro); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig*., MDL No. 2327, 2016 WL 4493666, at *4 n.2 (S.D.W. Va. Aug. 25, 2016) (same as to Dr. Toglia); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4493681, at *3 n.2 (S.D.W. Va. Aug. 25, 2016) (same as to Dr. Pramudji).

Dr. Horbach's common-knowledge opinions are also consistent with the legal principle that there is no duty to warn of risks commonly known to surgeons who use the device. 21 C.F.R. § 801.109(c) (providing that information may be omitted from labeling for a prescription device "if, but only if, the article is a device for which directions, hazards, warnings, and other

information are commonly known to practitioners licensed by law to use the device.").[1] While Dr. Horbach will not testify as to the requirements of this regulation, she is uniquely qualified by her medical education and training to testify about what is within the common knowledge of physicians who perform pelvic-floor surgeries. Indeed, only a physician with such training and experience could testify as to common knowledge of surgeons who perform these surgeries. *See also Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 720–21 (S.D.W. Va. 2014) (permitting Dr. Blaivas to testify as to "Other Physicians's Knowledge" because, "[a]s a urologist, Dr. Blaivas is certainly fit to testify what other physicians knew as it relates to the standard of care for designing a mesh product and *warning about its potential risks*" (emphasis added)).

Because Dr. Horbach will limit her testimony on this topic in accordance with the Court's ruling, this Court should deny this aspect of Plaintiffs' motion as moot.

VI. Plaintiffs' objection to unidentified expert opinions is improper.

Plaintiffs appear to renew their Wave 1 objection to unspecified "Opinions that Do Not Properly Identify the Source of the Opinion." *See* Pls.' Mem. (Dkt. 2045) at 15. This Court stated it "will not make speculative or advisory rulings" and "decline[d] to exclude testimony where the party seeking exclusion does not provide specific content or context." *In re: Ethicon Inc.*, 2016 WL 4582210, at *6. Inasmuch as Plaintiffs have not provided that content or context, Ethicon respectfully requests that the Court rule in the same manner in the Wave 3 cases and again deny this portion of Plaintiffs' motion.

---

[1] Moreover, this testimony will be helpful to juries assessing warning adequacy because a manufacturer has no duty to warn of risks commonly known to the surgeons who use the device. As stated generally in the Restatement (Third) of Torts: Products Liability § 2 cmt. j, a product seller "is not subject to liability for failing to warn or instruct regarding risks and risk-avoidance measures that should be obvious to, or generally known by, foreseeable product users." *See also* RESTATEMENT (SECOND) OF TORTS §§ 388(b), 402A cmt. j.

CONCLUSION

For the foregoing reasons, Ethicon respectfully requests that Plaintiffs' motion be denied in its entirety or limited as set forth above.

Respectfully submitted,

ETHICON, INC. AND
JOHNSON & JOHNSON

/s/ Rita A. Maimbourg
Rita A. Maimbourg
TUCKER ELLIS LLP
950 Main Avenue, Suite 1100
Cleveland, OH 44113-7213
Tel: 216.592.5000
Fax: 216.592.5002
rita.maimbourg@tuckerellis.com

/s/ David B. Thomas
David B. Thomas (W.Va. Bar #3731)
THOMAS COMBS & SPANN PLLC
300 Summers St.
Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 25338
Tel: 304.414.1807
dthomas@tcspllc.com

/s/ Christy D. Jones
Christy D. Jones
BUTLER SNOW LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
Tel: 601.985.4523
christy.jones@butlersnow.com

CERTIFICATE OF SERVICE

I certify that on October 10, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ *Rita A. Maimbourg*
Rita A. Maimbourg
TUCKER ELLIS LLP
950 Main Avenue, Suite 1100
Cleveland, OH 44113-7213
Tel: 216.592.5000
Fax: 216.592.5002
rita.maimbourg@tuckerellis.com